Federal Public & Community Defenders
Legislative Committee

52 Duane Street, 10th Floor
New York, NY 1007
Tel: (212) 417-8738

Co-Chairs

David Patton
Executive Director
Federal Defenders of New York

Jon Sands
Federal Defender
District of Arizona

March 2, 2021

Alyssa M. Hundrup
Acting Director, Health Care, United States Government Accountability Office (GAO)
441 G St. N.W.
Washington, D.C. 20548

Re: Response to GAO Report on Synthetic Opioids: Considerations for Class-Wide Scheduling of Fentanyl-Related Substances (GAO-21-301SU)

Dear Ms. Hundrup:

Thank you for providing the Federal Public and Community Defenders a copy of GAO's draft report on the class-wide scheduling of fentanyl-related substances ("Report")[1] and for the opportunity to comment on its findings. The Report has the potential to offer a critical contribution to the policy discussion surrounding class-wide scheduling of fentanyl-related substances and the best way to respond to fentanyl and its analogues.[2] Unfortunately, the Report places too much emphasis on assertions by law enforcement about the utility and effect of class-wide scheduling and not enough on the GAO's carefully gathered evidence and findings that demonstrate class-wide scheduling is unnecessary and could lead to over-criminalization. As detailed below, we urge the GAO to revise the Report to provide more emphasis on its own core findings.

I. The Report confirms that the government is well-equipped to prosecute fentanyl analogues without class-wide scheduling.

The Report's Executive Summary ("Highlights") should specify that harmful fentanyl-related substances are already illegal even without class-wide scheduling. Presently, the Highlights section states that "allowing the temporary scheduling order to expire . . . would mean relying on DEA to

[1] U.S. Gov't Accountability Office, GAO-21-301SU, Synthetic Opioids: Considerations for Class-wide Scheduling of Fentanyl-Related Substances (Feb. 2021) (Draft) ("Report").

[2] This comment refers to "fentanyl-related substances" and "fentanyl analogues." The term "fentanyl-related substances" refers to the specific substances that are defined in the temporary scheduling order that was codified, temporarily, by legislation. *See,* 83 Fed. Reg. 5188 (Feb. 6, 2018); Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, Pub. L. No. 116-114 (2020). The term "fentanyl analogues" refers to "synthetic opioids with chemical structures related to fentanyl—including fentanyl analogues that have been scheduled and fentanyl-related substances." Report at 3.

52 Duane Street, 10th Floor
New York, NY 1007
Tel: (212) 417-8738

individually schedule specific fentanyl substances, as DEA has done in the past."[3] This framing perpetuates the false claim[4] that the government cannot already effectively prosecute cases involving fentanyl-related substances and fentanyl analogues.

The Report feeds this false claim in two ways. First, the Report fails to adequately emphasize that the Department of Justice ("Department") and federal law enforcement agencies have rarely relied on class-wide scheduling. From 2019 to 2020, most fentanyl-analogue prosecutions involved "analogues that had been individually scheduled prior to class-wide scheduling."[5] In contrast, the Department prosecuted only eight cases under the class-wide control since its adoption in 2018.[6] This breakdown confirms that most fentanyl-analogue prosecutions have involved substances that the government used long-existing scheduling authorities[7] to individually control and that the Department's repeated claim that class-wide scheduling is necessary for effective enforcement lacks factual support.[8]

Second, the Highlights section omit any mention of the Analogue Act. The Analogue Act equips federal law enforcement to interdict and prosecute fentanyl analogues that are not already

[3] Report, Highlights. The Report includes other similarly misleading statements. For instance, the DEA told GAO "if class-wide scheduling expires, fentanyl-related substances would no longer be scheduled and criminal organizations would likely resume or increase production of these substances." Report, App. IV at 50. The Report footnotes DEA's statement with a reference to the Analogue Act, but in that note, reiterates law enforcement complaints about the Analogue Act.

[4] See Fentanyl Analogues: Perspectives on Classwide Scheduling: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Security of the H. Comm. on the Judiciary, 116th Cong. 4 n.18 (Jan. 2020)(Testimony of Kevin L. Butler, Fed. Pub. Defender for the Northern District of Alabama,) ("Butler Test."), https://www.congress.gov/116/meeting/house/110392/witnesses/HHRG-116-JU08-Wstate-ButlerK-20200128.pdf (summarizing claims by law enforcement and the Department of Justice that harmful fentanyl analogues would be legalized without class-wide control); Nancy Gertner, *William Barr's New War on Drugs*, Wash. Post, Jan. 26, 2020, https://www.washingtonpost.com/opinions/2020/01/26/william-barrs-new-war-drugs/ ("[Attorney General] Barr recently warned that if his request were not granted, illicit fentanyl analogues would be 'legal.' That is false. Dangerous fentanyl analogues have long been illegal and will continue to be under existing laws.").

[5] Report, App. IV at 60 ("EOUSA officials told us that most of the fentanyl analogue cases prosecuted were for offenses involving analogues that had been individually scheduled prior to class-wide scheduling.").

[6] *Id.* at 54; *see also* U.S. Sentencing Comm'n, *Fentanyl and Fentanyl Analogues: Federal Trends and Trafficking Patterns* at 23 (Jan. 2021) ("USSC Report"), https://www.ussc.gov/sites/default/files/pdf/research-and-publications/research-publications/2021/20210125_Fentanyl-Report.pdf ("Most of the substances identified in the fiscal year 2019 sentencing documents as "fentanyl analogues" are substances listed in a schedule of the CSA before publication of the DEA's [class-wide scheduling] order.").

[7] DEA has been empowered to schedule substances administratively based on a scientific and medical evaluation of a substance from the Assistant Secretary for Health since 1970 and to do so on an accelerated basis since 1984. *See* 21 U.S.C. § 811; Thomas M. Quinn & Gerald T. McLaughlin, *The Evolution of Federal Drug Control Legislation*, 22 Cath. U. L. Rev. 586, 607–08 (1973); Comprehensive Crime Control Act of 1984, Pub. L. No. 98-473, tit. II, 98 Stat. 1976 (Oct. 12, 1984).

[8] Nor has class-wide control meaningfully impacted law enforcement investigations. "Officials from all four DEA field division offices and four OCDETF strike forces . . . indicated that, overall, class-wide scheduling has not or would not have a substantial effect on how they conduct investigations involving fentanyl-related substances, such as the time and resources needed to investigate cases." Report, App. IV at 53.

52 Duane Street, 10th Floor
New York, NY 1007
Tel: (212) 417-8738

scheduled—further undermining the need for class-wide scheduling.[9] We would expect this existing statutory method of prosecuting unscheduled fentanyl analogues to be at the forefront of the Report's discussion. It is not mentioned until page 12. And the Report emphasizes Department complaints that Analogue Act prosecutions for fentanyl analogues will be unwieldy and unnecessarily resource-intensive—concerns that lack factual support.[10] According to the Department, prosecutor reliance "on the [Analogue Act] to charge offenses involving fentanyl-related substances and cases for the same substance could generate inconsistent jury findings,"[11] and "prosecutors who use the [Analogue Act] have little certainty that a jury will find the substance is an analogue though they are expending a great deal of time and resources to prosecute cases."[12] But despite these concerns, there is little information about how often the Department has relied on the Analogue Act to prosecute fentanyl analogues and the Department did not provide to GAO any case-specific examples to support its claims.[13] Further, the Report does not include Defender statements that we were unable to identify any examples of cases that support the Department's concerns. We found no cases involving a resource-intensive "battle of the experts" over the identity of a purported fentanyl-related substance, nor examples where juries or courts reached different conclusions about whether a fentanyl-related substance was or was not an analogue.

Overcoming an individual's presumption of innocence is not intended to be convenient for the government. The Analogue Act requires the government to prove that a novel substance meets the Controlled Substance Act's definition of "controlled substance analogue" before that person can be convicted and punished.[14] Congress carefully designed the elements of that definition to secure convictions for dangerous novel substances while shielding harmless conduct from criminal sanctions.[15] The Report should emphasize that despite the Department's claims to the contrary, all evidence indicates the implementation of the Analogue Act has successfully achieved this balance, and that class-wide scheduling would disrupt it.

---

[9] The Analogue Act, 21 U.S.C. § 813, controls substances that are not otherwise scheduled or FDA-approved that are intended for human consumption if it has (1) a chemical structure substantially similar to that of a controlled substance in Schedule I or II, and (2) an actual, represented, or intended effect that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect of a controlled substance in Schedule I or II. Report at 12–13. As in every criminal case, prosecutors are required to meet their burden of proof with respect to the elements of the offense under the Analogue Act.

[10] *See e.g.*, Report at 18; App. IV at 55-56.

[11] *See* Report, App. IV at 55, Report at 18.

[12] *Id.*

[13] *See Id.* at 55 n. 85 (The Department provided GAO an example of three Analogue Act cases that resulted in inconsistent outcomes, but "[n]one of these cases involved a fentanyl analogue or fentanyl-related substance.").

[14] *See id.* at 12–13.

[15] Butler Test. at 9-10 (summarizing legislative history of the Analogue Act, including consideration by Congress of testimony from the American Chemical Society).

52 Duane Street, 10th Floor
New York, NY 1007
Tel: (212) 417-8738

II. The Report should prominently state that GAO could not substantiate law-enforcement claims that class-wide scheduling has a causal connection to reduced encounters with novel fentanyl-related substances.

The Report repeatedly highlights law enforcement claims about the efficacy of class-wide scheduling but buries the finding that GAO could not substantiate those claims. The Report's Highlights and body repeat that "Federal law enforcement officials said that a benefit of class-wide scheduling—reduced incentives for traffickers to make new and existing fentanyl-related substances to circumvent the law—would be lost if substances were scheduled individually."[16] In contrast, the Report obscures in footnotes and appendices that GAO was "unable to draw any causal conclusions related to class-wide scheduling" and law enforcement encounters,[17] and that "the number of reports of all fentanyl analogues and other related compounds (e.g., precursors), including individually scheduled analogues, have *increased* since the implementation of class-wide scheduling."[18] Front-loading law enforcement's claims, without similar attention to these important factual findings, may lead many readers to wrongly conclude that GAO substantiated these law enforcement assertions.

We urge the authors to add language in the Highlights and in the body of the Report to clarify its findings and directly confront these claims with the absence of factual support.

III. The Report should highlight evidence that class-wide scheduling would improperly criminalize helpful and harmless substances.

The Report should emphasize that class-wide scheduling "preemptively classifi[es] an unknown number of similar substances with unknown effects,"[19] including harmless and therapeutic substances. The class-wide control defines fentanyl-related substances "based on their chemical structure alone and [does] not define them based on their pharmacological activity—the resulting physical and psychoactive effects on humans."[20] This is a flawed approach because chemical structure alone cannot predict how a drug will affect the human brain.[21] The relative potency of fentanyl and fentanyl analogues varies widely: "[s]ome analogues, like acetyl fentanyl, are less potent

---

[16] *See* Report at "Highlights"; 20.

[17] Report, App. I: at 28 n.27; *see also*, Report, App. IV at 50, 52–53 ("Although the timing of DEA's temporary order corresponds to a decrease in law enforcement reports of new and existing fentanyl analogues that are not individually scheduled, we are unable to draw conclusions about the extent to which the cause of the decrease is related to class-wide scheduling. This is because of the short time period that the order has been in effect and the numerous other factors that could affect law enforcement reports of these analogues, including fentanyl-related substances.").

[18] Report, App. IV at 51 n.73 (emphasis added); *see also, id.* at 62 ("Overall seizures of fentanyl and its analogues entering at U.S. ports of entry increased substantially from fiscal year 2018 through fiscal year 2020.")(emphasis added).

[19] *Id.* at 16.

[20] Report, App. II at 31.

[21] See Fentanyl Analogues: Perspectives on Classwide Scheduling: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Security of the H. Comm. on the Judiciary, 116th Cong. 4 (Testimony of Dr. Sandra D. Comer, Professor of Neurobiology (in Psychiatry), Columbia University Irving Medical Center, New York State Psychiatric Institute) (Jan. 28, 2020), https://docs.house.gov/meetings/JU/JU08/20200128/110392/HHRG-116-JU08-Wstate-ComerS-20200128.pdf.

52 Duane Street, 10th Floor
New York, NY 1007
Tel: (212) 417-8738

than fentanyl; others, like carfentanil, are many times more potent; and still others, like benzylfentanyl, are believed to be essentially biologically inactive."[22] There are already examples of the class-wide control's overbreadth: the Report identifies specific substances that meet the criteria for class-wide control that have "little to no pharmacological potential for abuse,"[23] as does recent scientific research.[24]

Under the class-wide control, any offense involving a fentanyl-related substance is subject to federal criminal prosecution, even if the substance in question has no potential for abuse. This approach would result in convictions for substances that may not have a psychoactive effect similar to fentanyl.[25] The Report minimizes these concerns and repeats the Department's assertions that it will not prosecute individuals for substances that are not harmful.[26] But a careful reading of the Report also shows that these assurances cannot be credited: as acknowledged (in a footnote), after 2018, the government prosecuted cases involving benzyl fentanyl,[27] a substance long known to have no potential for abuse.[28] If class-wide scheduling becomes permanent, prosecutors will have no incentive to determine whether or not a substance has abuse potential. Nor are prosecutors

[22] Kemp Chester, Assoc. Dir., Nat'l Heroin Coordination Grp., Off. of Nat'l Drug Control Pol'y, Response to Questions for the Record Following Hearing Entitled, The Countdown: Fentanyl Analogues & the Expiring Emergency Scheduling Order to S. Comm. on the Judiciary (June 4, 2019) at 3, https://www.judiciary.senate.gov/imo/media/doc/Chester%20Responses%20to%20QFRs1.pdf.

[23] Report, App. III ("[S]mall changes can produce substances with little to no pharmacological potential for abuse—*as was found for two fentanyl analogues cited by DEA in the temporary scheduling order for fentanyl-related substances.*").

[24] Dr. Sandra D. Comer et. al., *Potential unintended consequences of class-wide drug scheduling based on chemical structure: A cautionary tale for fentanyl-related compounds*, Drug and Alcohol Dependence, 3 (2021), https://www.sciencedirect.com/science/article/pii/S0376871621000259.

[25] Report, App. IV at 57.

[26] *Id.* at 57 n.88.

[27] In 1985, the DEA temporarily placed benzyl fentanyl on Schedule I based on its structure, but later removed it from control after "further research found no evidence of abuse potential." Drug Enf't Admin. Correction of Code of Federal Regulations: *Removal of Temporary Listing of Benzylfentanyl and Thenylfentanyl as Controlled Substances*, 21 C.F.R. § 1308 (2010).. In 2019, DEA classified benzyl fentanyl as a "List I" chemical, meaning that it is an ingredient that can be used to create fentanyl analogues. *See* Drug Enf't Admin., *Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals*, 85 Federal Register 73 at 20822-20829, (April 15, 2020), https://www.deadiversion.usdoj.gov/fed_regs/rules/2020/fr0415.htm. In contrast to Schedule I fentanyl analogues, the potential sentences for distribution of List I chemicals are largely capped at five years. *See* 21 U.S.C. § 841(f)(1) ("Whoever knowingly distributes a listed chemical in violation of this subchapter (other than in violation of a recordkeeping or reporting requirement of section 830 of this title) shall, except to the extent that paragraph (12), (13), or (14) of section 842(a) of this title applies, be fined under title 18 or imprisoned not more than 5 years, or both.")

28 Report, App. IV at 57 n.89 ("[r]epresentatives provided [the GAO] examples of at least three cases where individuals were prosecuted for the substance benzyl fentanyl which has no pharmacological effect. They stated that, in one instance, prosecutors sought the mandatory minimum associated with the charge"). The USSC Report confirms this, finding that after the 2018 temporary control, the government prosecuted "several cases involving . . . benzyl fentanyl." *See* USSC Report at 23.

52 Duane Street, 10th Floor
New York, NY 1007
Tel: (212) 417-8738

equipped to make such assessments, particularly for substances under class-wide control, which would be scheduled without gathering and reviewing scientific evidence.[29]

The Report should highlight the implications of criminalizing substances with no potential for abuse.

IV. The Report minimizes concerns that fentanyl and fentanyl-analogue prosecutions would continue to target minimally-involved individuals and street-level dealers, an enforcement approach that exacerbates racial disparities and does not deter drug trafficking organizations.

We urge the GAO to devote further discussion and analysis to the fact that prosecutions for fentanyl analogues disproportionately target minimally-involved individuals and street-level dealers.[30] The evidence compiled in the Report and in a recently-published report by the United States Sentencing Commission shows that most enforcement efforts have targeted low-level individuals.[31] And there is overwhelming evidence that incapacitating low-level individuals does not disincentivize drug trafficking organizations.[32] Class-wide scheduling needs to be understood, and should be framed in the Report, as another failed effort to fight the war on drugs by prosecuting low-level individuals and punishing them with disproportionately long sentences.[33]

The Report presently cabins these systemic concerns to a few sentences,[34] but devotes significant discussion to uncritically highlighting statements from law enforcement that "one of the goals of class-wide scheduling was to disincentivize drug trafficking organizations to invent new fentanyl-related substances to evade DEA's control," and that law enforcement's goal is to "dismantle the entire organization."[35] The Report also includes a potentially misleading note that "out of the eight cases we reviewed that were prosecuted under class-wide scheduling, four involved a defendant who was part of a larger drug trafficking organization."[36] This characterization omits the fact, included

---

[29] *See* Report at 16 ("If fentanyl-related substances are legislatively scheduled without an Eight-Factor Analysis being conducted, the Eight-Factor Analysis needed for administratively rescheduling these substances could involve more evidence than was required for the initial legislative scheduling.").

[30] *Id.*, Report, App. IV at 59.

[31] *See id.* at 54; USSC Report at 28.

[32] Nat'l Resch. Council, The Growth of Incarceration in the United States: Exploring Causes and Consequences 146 (Jeremy Travis et al. eds., 2014), http://nap.edu/catalog.php?record_id=18613; Pew, *More Imprisonment Does Not Reduce State Drug Problems*, (March 8, 2018), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/03/more-imprisonment-does-not-reduce-state-drug-problems; USSC, *Fifteen Years of Guidelines Sentencing: An Assessment of How Well the Federal Criminal Justice System is Achieving the Goals of Sentencing Reform* 131 (2004), https://www.ussc.gov/sites/default/files/pdf/research-and-publications/research-projects-and-surveys/miscellaneous/15-year-study/15_year_study_full.pdf; *see also* Butler Test. at 12-14.

[33] Butler Test. at 7.

[34] *See id.* at 19, Report, App. IV at 59.

[35] *See, e.g.*, Report, App. IV at 59.

[36] *Id.*

52 Duane Street, 10th Floor
New York, NY 1007
Tel: (212) 417-8738

elsewhere in the Report, that each of those four individuals was a street-level dealer, and that the government has not used class-wide scheduling to prosecute even one high-level importer, supplier, or drug kingpin.[37] Targeting street-level dealers for prosecution disproportionately impacts people of color, particularly Black Americans, all while failing to reduce the supply of or demand for illegal drugs.[38]

V. The Interagency Working Group's ("Interagency Group") proposal would not address the criminal justice implications of class-wide scheduling.

The Report suggests that "fentanyl-related substances could be legislatively scheduled with modifications"[39] to the class-wide control, and points to recommendations made by an "interagency workgroup convened by ONDCP . . . such as removing barriers to obtaining approval to conduct research and streamlining the process for removing from Schedule I . . .substances discovered to have low abuse potential."[40] We request GAO include both in the Highlights and in the Report Defenders' concerns that the Interagency Group's proposal would not remediate the flawed enforcement-first approach embraced by class-wide control, would lead to lengthy sentences for trace amounts of fentanyl-related substances, and would exacerbate racial disparities in federal sentencing. The Interagency Group's proposal also does not relieve concerns that class-wide scheduling would criminalize substances with no potential for abuse. Although it would attempt to "streamlin[e] the process for removing from Schedule I [] substances discovered to have low abuse potential," de-scheduling would not vacate sentences imposed for such substances.[41]

The shortcomings in the Interagency Group's proposal may be the result of its failure to seek the views of Federal Public and Community Defenders or of the civil rights and criminal justice community. Similarly, the GAO did not seek these perspectives on the Interagency Group's Proposal. The Report should note that these critical voices were neither present during the creation of the Interagency Group recommendations nor were we given an opportunity to comment on the proposal through the Report.

---

[37] *Id.* at 54.

[38] Pew, *More Imprisonment Does Not Reduce State Drug Problems* (March 8, 2018), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/03/more-imprisonment-does-not-reduce-state-drug-problems.

[39] Report, Highlights.

[40] *Id.*

[41] *See* 1 U.S.C. § 109 (providing that if a statute is changed or repealed after a crime is committed, "it shall not have the effect to release or extinguish any penalty, forfeiture, or liability incurred under such statute").

52 Duane Street, 10th Floor
New York, NY 1007
Tel: (212) 417-8738

We hope that the GAO will modify the Report to reflect our comments. We remain available to discuss our perspectives and experience on this issue as needed.

Sincerely,

/s/
David Patton
Executive Director, Federal Defenders of New York
Co-Chair, Federal Defender Legislative Committee

/s/
Jon Sands
Federal Public Defender for the
District of Arizona
Co-Chair, Federal Defender Legislative Committee